REMARKS

Applicant respectfully requests reconsideration of the present case in view of the above amendments and the following remarks. Claims 21 and 23 have been amended to further clarify the claimed invention. Claims 25 to 29 are newly presented. After entry of the amendments, claims 18 and 20-29 will be pending.

Applicant submits the amendment is supported by the specification and does not raise any issues of new matter.

35 U.S.C. § 103

Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Lacroix, and Seidel

Claims 18 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Masalova and Papatheodoridis, or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further in view of either Lacroix or Seidel et al. Applicant respectfully traverses this rejection.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP § 2142. Three criteria must be met by the Examiner to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference or references must teach or suggest all the claim limitations. In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). At minimum, the Office Action has failed to establish a motivation to combine the teachings of the cited references

The Office Action alleges the method disclosed by Ling is only limited in that the two different immunoreactants used to detect the antigen and antibody in the sample must be non-complimentary to each other. The Office Action further alleges that Schönbrunner teaches that multiple epitopes may be found on the same protein antigen. Based on the combined teachings of Ling and Schönbrunner, the Office Action concludes is would have been obvious to one of ordinary skill in the art that a first antibody that binds to an epitope not found in the first peptide,

but that may be found on the same protein antigen from which the peptide was derived, may be used in combination with the first peptide. Applicant respectfully does not agree.

A novel feature of the present claims is the relationship between the first analyte antigen and the second analyte antibody, in that the second analyte antibody is an antibody to the first analyte antigen. Such an assay system, however, can be accompanied by the following difficulties:

(1) To prepare the assay system, both the antibody to capture a first analyte antigen and the antigen to capture a second analyte antibody must be immobilized to the same solid phase. During the immobilization, the antibody to be immobilized and the antigen to be immobilized could react with each other, resulting in adverse effects on the assay result.

(2) To detect a first analyte antigen captured to the immobilized antibody, a labeled antibody to the antigen must be added to the assay system. In this case, the added labeled antibody could react with the immobilized antigen for capturing the second analyte antibody, resulting in an incorrect assay result.

To avoid the above-mentioned difficulties, the present claims recite an HCV core antigen to detect core antibodies wherein the antigen lacks epitopes recognized by said antibodies for detection of HCV core antigen. No cited reference teaches or suggests this feature.

Schönbrunner teaches away from using a single class of antigen to detect virus in a simultaneous detection assay. In order to prevent false positives and/or false negatives, Schönbrunner discloses a simultaneous detection assay that detects (1) a first class of antigen in the specimen and (2) antibody to a second class of antigen in the specimen that is different than the first antigen (Schönbrunner at page 5, line 33 to page 6, line 13). For example, Schönbrunner discloses that if the first analyte is a gag antigen, the second analyte is an anti-capsid antibody or anti-envelope antibody. Schönbrunner therefore teaches away from a detection assay that includes, for example, a first analyte that is a p7 antigen and a second analyte that is an anti-p7 antibody.

In view of the teachings of Schönbrunner discussed above, Applicant submits the combination of Ling and Schönbrunner teaches away from the claimed invention. As evidenced by Ling and Schönbrunner, one of skill in the art would not have been motivated to combine or

modify the references to arrive at the claimed invention. Ling and Schönbrunner suggest selecting an antigen as the first analyte and an antibody as the second analyte so that the second analyte antibody is not an antibody to the first analyte antigen, so as to avoid false-positive or false-negative assay results. For example, Schönbrunner discloses using a P" antigen in combination with P24 antigen or gp41 antigen. Ling discloses using HBs antigen in combination with HBc antigen. None of the cited references teach or suggest selecting an antigen as the first analyte and an antibody as the second analyte so that the second analyte antibody is an antibody to the first analyte antigen. Therefore, absent Applicant's teachings, there is no motivation to combine the disclosures of Masalova and Papatheodoridis, or of Simmonds, with Ling and Schönbrunner.

Absent the combination of Ling and Schönbrunner, there is no motivation to combine the disclosure of Masalova and Papatheodoridis, or of Simmonds, with Seidel or Lacroix. Lacroix and Seidel do not describe or suggest selecting an antigen as the first analyte and an antibody as the second analyte so that the second analyte antibody is an antibody to the first analyte antigen.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also contains a motivation or suggestion to modify or combine the references. *In re Mills*, 916 F.2d 680, 682 (Fed. Cir. 1990). Absent Applicant's disclosure, one of skill in the art would not have been motivated to combine the references as recited in the Office Action. Therefore, the Office Action has failed to establish a *prima facie* case of obviousness. Withdrawal of the rejection is respectfully requested.

Insofar as the rejection applies to new claims 25-29, Applicant submits the Office Action has failed to establish a *prima facie* case of obviousness based on the combination of Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner for the reasons discussed above.

Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Cheng, and Khanna

Claims 21 and 23 were rejected under 35 U.S.C. § 103(a) as being unpatentable over either of Masalova and Papatheodoridis or of Simmonds, in view of Ling and Schönbrunner as applied to claim 18 above, and further view of either of Cheng or Khanna. Applicant respectfully traverses this rejection.

In the interest of advancing prosecution, Applicant has amended claims 21 and 23 to recite the class or dilution of non-ionic surfactants. Applicant does not however acquiesce to the rejection. Withdrawal of the rejection is respectfully requested.

Insofar as the rejection applies to new claims 25-29, Applicant submits the Office Action has failed to establish a *prima facie* case of obviousness based on the combination of Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner for the reasons discussed above.

Cheng and Khanna do not cure the deficiencies of Masalova, Papatheodoridis, Simmonds, Ling and Schönbrunner. Cheng and Khanna show the use of detergents in the case of use as analyte-biotin bidentate reagent or in the case of decreasing complex formation. However, these uses are completely different from the use in the present invention. In addition, Cheng describes on column 7, lines 26 to 35, "the detergent(s) that may be employed in accordance with the methods of the present invention include anionic detergents, cationic detergents(s), Zwitterionic detergents, and nonionic detergents." Therefore, Cheng provides no expectation of success because it merely provides a blanket disclosure of all kinds of detergents without identifying any in particular for use as claimed and without providing any expectation that any particular detergents would work with the invention as claimed.

In view of the forgoing, Applicants assert that the combination of Masalova, Papatheodoridis, Simmonds, Ling, Schönbrunner, Cheng and Khanna fails render to the claims obvious.

Summary

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Brian H. Batzli
Reg. No. 32,960
Merchant & Gould P.C.
P. O. Box 2903
Minneapolis, MN 55402-0903
612.336.4755